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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/333,256	06/15/1999	JURGEN ENGEL	PM26021897/2	3896

909 7590 11/06/2002

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.
09/333,256

Applicant(s)
Engel et al.

Examiner
Susan T. Tran

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Oct 15, 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on Oct 15, 2002. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
see attachment

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1-6

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

10. ☐ Other: _____

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ADVISORY ACTION

Receipt is acknowledged of applicants Fee and Declaration filed 9/9/99, Requested for Extension of Time filed 08/28/00, 05/07/01, 03/18/02 and 10/15/02, Amendment A filed 08/28/00, Amendment B filed 10/24/00, Notice of Appeal filed 05/07/01 and 10/15/02, Request for Reconsideration filed 03/18/02 10/15/02.

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Battistini et al. US 5,905,149.

Battistini discloses a film-coated tablet composition comprising diluents, e.g., lactose, corn starch, or cellulose; lubricants, e.g., magnesium stearate, silica; and binding agents, e.g., starches, or cellulose (column 11, lines 1-30). The composition further comprising antitumor agent, e.g., cyclophosphamide (column 12, lines 4-8).

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Claim Rejections - 35 U.S.C. § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al., in view of Eugster et al. US 5,593,691.

Battistini is relied upon for the reasons stated above. Regarding to claims 4-6, the cited reference is silent as to the teaching of the amounts of the ingredients.

Eugster teaches a coated tablet composition comprising active agent; excipient, filler; binder such as corn starch; flow-control; talc or magnesium stearate (column 21, lines 32 through column 22, lines 1-11). The active agent is an antitumor agent, e.g., cyclophosphamide (column 11, lines 54-56). The amounts of the ingredients are disclosed in column 32, lines 30-35. Thus, it would have been prima facie obvious for one of the ordinary skill in the art to modify Battistini's tablet composition using the amounts for the ingredients in view of the teaching of Eugster. The reason for this modification is to obtain a stable film coated tablet of cyclophosphamide.

The exclusion of pre-swollen starch does not impart patentable distinct, since the prior art obtains the same results desired by applicants, i.e., a coated tablet containing phosphamide having excellent stability and bioavailability. Thus, it would have been obvious for one of the

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ordinary skill in this art to, by routine experimentation determine a suitable type of starch to obtain a stable composition of phosphamide, since phosphamide is known to the skill in the art to be an unstable active compound.

Response to Arguments

3. Applicant's arguments filed 10/15/02 have been fully considered but they are not persuasive. The examiner maintains the original rejections.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Battistini et al. US 5,905,149.

Applicant interpreted the term “pre-swollen starch” to conclude that Battistini teaches *part* of the starch is pre-swollen. In the final office action dated 04/15/2002, the examiner indicated that “part” of the starch (10 grams out of 415 grams) is suspended in water (to form a starchy paste). Nonetheless, the remaining quantity of the starch (405 grams) is added to a dried granulated powder along with talc, magnesium stearate to process into tablet. Accordingly, such language does suggest that the remaining quantity of the starch is dry, not suspend in warm water, and therefore, not swollen. Applicant’s claim recites the phrase “wherein at least one of the fillers is lactose monohydrate and no pre-swollen starch is present as a dry binder”. First of all, the transitional phrase “comprising of”, which is synonymous with “including,” “containing,” or “characterized by,” is inclusive or open-ended and does not exclude additional, unrecited elements . *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 229 USPQ 805 (Fed. Cir.

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1986); *In re Baxter*, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)(“comprising” leaves “the claim open for the inclusion of unspecified ingredients even in major amounts”). Secondly, the phrase “no pre-swollen starch is present as a dry binder” only exclude pre-swollen starch present as a dry binder, not fillers, not flow regulators, not lubricants. Moreover, the claim can be read as that, at least one of the fillers, one or more flow regulators, one or more lubricants can include starch, *e.g.*, pre-swollen starch and/or non-swollen starch. Battistini discloses starch as diluent, as well as disaggregating agent, and therefore, 10 grams of pre-swollen starch could have been used as diluent and/or disaggregating agents. The teaching of Battistini regarding the remaining dry/non-suspended/non-swollen starch clearly falls within the claimed limitation as a dry binder, and thus, the claim is clearly anticipated.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battistini et al., in view of Eugster et al. US 5,593,691.

Applicant argues that Eugster neither teaches nor suggests applicant's invention. In response to applicant's argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347,

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21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Eugster is relied upon solely for the teaching of the amounts of the ingredients.

Applicant argues that exclusion of a claimed component, pre-swollen starch, must be motivated by the teachings of the cited references. The applicants have shown that exclusion of pre-swollen starch results in unexpectedly improved stability of cyclophosphamide and reduced discoloration of the disclosed compositions. In response to applicant's argument, assuming *arguendo*, applicant's claim limits the scope of the claim to exclude "pre-swollen starch" characteristic(s)" of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. *The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.*). The "comprising of" is a fully open claims format. *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an

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applicant contends that additional steps or materials in the prior art are excluded by the recitation of the claim, applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). Eugster does suggest the stability characteristics of the pharmaceutical composition comprising antitumor agent, *e.g.*, cyclophosphamide.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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